Proposed Registration Decision PRD2010-10

(E,Z)-11-tetradecenal

(publié aussi en français)

7 July 2010

This document is published by the Health Canada Pest Management Regulatory Agency. For further information, please contact:

Publications
Pest Management Regulatory Agency
Health Canada
2720 Riverside Drive
A.L. 6604-E2
Ottawa, Ontario
K1A 0K9

Internet: pmra.publications@hc-sc.gc.ca
healthcanada.gc.ca/pmra
Facsimile: 613-736-3758
Information Service:
1-800-267-6315 or 613-736-3799
pmra.infoserv@hc-sc.gc.ca

Canada

HC Pub: 100236

ISBN: 978-1-100-15822-8 (978-1-100-15823-5)
Catalogue number: H113-9/2010-10E (H113-9/2010-10E-PDF)

© Her Majesty the Queen in Right of Canada, represented by the Minister of Health Canada, 2010

All rights reserved. No part of this information (publication or product) may be reproduced or transmitted in any form or by any means, electronic, mechanical, photocopying, recording or otherwise, or stored in a retrieval system, without prior written permission of the Minister of Public Works and Government Services Canada, Ottawa, Ontario K1A 0S5.

Proposed Registration Decision for (E,Z)-11-tetradecenal

Health Canada's Pest Management Regulatory Agency (PMRA), under the authority of the Pest Control Products Act and Regulations, is proposing a renewal of the conditional registration for Bedoukian Spruce Budworm Technical Pheromone and Hercon Disrupt Micro-Flake SBW Spruce Budworm Mating Disruptant containing the technical grade active ingredient compound (E,Z)-11-tetradecenal to disrupt the mating of spruce budworm moths.

Bedoukian Spruce Budworm Technical Pheromone (Registration Number 28694) and Hercon Disrupt Micro-Flake SBW Spruce Budworm Mating Disruptant (Registration Number 28695) were granted a conditional registration in Canada in 2007. The detailed review for Bedoukian Spruce Budworm Technical Pheromone and Hercon Disrupt Micro-Flake SBW Spruce Budworm Mating Disruptant can be found in Evaluation Report ERC2007-07, (E,Z)-11-tetradecenal. The original evaluation of available scientific information found that, under the approved conditions of use, the product has value and does not present an unacceptable risk to human health or the environment.

Although the risks and value have been found acceptable when all risk reduction measures are followed, as a condition of the original registrations, additional scientific information was requested from the applicant to be submitted by December 2008. In support of the request to renew the conditional registrations, a rationale for renewal of the registration in the absence of required data or information was provided. Based on a review of the submitted rationale, the request to renew the conditional registrations is granted until December 31, 2011. The requirement to submit additional scientific information as a condition of registration remains.

The Overview describes the key points of the original evaluation, while the Science Evaluation in ERC2007-07 provides detailed technical information on the human health, environmental and value assessments of (E,Z)-11-tetradecenal and the end-use product Hercon Disrupt Micro-Flake SBW Spruce Budworm Mating Disruptant.

What Does Health Canada Consider When Making a Registration Decision?

The key objective of the *Pest Control Products Act* is to prevent unacceptable risks to people and the environment from the use of pest control products. Health or environmental risk is considered acceptable[1] if there is reasonable certainty that no harm to human health, future generations or the environment will result from use or exposure to the product under its proposed conditions of registration. The Act also requires that products have value[2] when used according to the label directions. Conditions of registration may include special precautionary measures on the product label to further reduce risk.

---

1 "Acceptable risks" as defined by subsection 2(2) of the *Pest Control Products Act*.

2 "Value" as defined by subsection 2(1) of the *Pest Control Products Act*: "the product's actual or potential contribution to pest management, taking into account its conditions or proposed conditions of registration, and includes the product's (*a*) efficacy; (*b*) effect on host organisms in connection with which it is intended to be used; and (*c*) health, safety and environmental benefits and social and economic impact."

To reach its decisions, the PMRA applies modern, rigorous risk-assessment methods and policies. These methods consider the unique characteristics of sensitive subpopulations in humans (e.g. children) as well as organisms in the environment (e.g. those most sensitive to environmental contaminants). These methods and policies also consider the nature of the effects observed and the uncertainties when predicting the impact of pesticides. For more information on how the PMRA regulates pesticides, the assessment process and risk-reduction programs, please visit the Pesticide and Pest Management portion of Health Canada's website at healthcanada.gc.ca/pmra.

Before making a final registration decision to renew the conditional registration of (E,Z)-11-tetradecenal, the PMRA will consider all comments received from the public in response to this consultation document[3]. The PMRA will then publish a Registration Decision[4] on (E,Z)-11-tetradecenal, which will include the decision, the reasons for it, a summary of comments received on the proposed final registration decision and the PMRA's response to these comments.

For more details on the information presented in this Overview, please refer to the Science Evaluation in ERC2007-07.

What is (E,Z)-11-tetradecenal?

(E,Z)-11-tetradecenal is the main component of the pheromone of spruce budworm moths. This pheromone is released by female spruce budworm moths and attracts males to the females for mating. The end-use product, Hercon Disrupt Micro-Flake SBW Spruce Budworm Mating
Disruptant, contains the pheromone in micro-flake carriers which are applied with aerial application equipment.

Health Considerations

Can Approved Uses of Hercon Disrupt Micro-Flake SBW Spruce Budworm Mating Disruptant Affect Human Health?

Spruce Budworm Technical Pheromone is unlikely to affect your health when Hercon Disrupt Micro-Flake SBW Spruce Budworm Mating Disruptant is used according to the label directions

When assessing the health risks of the product Hercon Disrupt Micro-Flake SBW Spruce Budworm Mating Disruptant, two key factors are considered: the toxicity of the product and the levels to which people may be exposed.

---

3 "Consultation statement" as required by subsection 28(2) of the *Pest Control Products Act*.

4 "Decision statement" as required by subsection 28(5) of the *Pest Control Products Act*.

The active ingredient, (E,Z)-11-tetradecenal, belongs to a group of compounds known as straight chain lepidopteran pheromones (SCLP). These pheromones are naturally occurring compounds that are produced by many lepidopteran insect species (i.e. moths and butterflies) to communicate chemically with other members of the same species.

In general, SCLPs are biodegraded to non-toxic compounds by enzyme systems that are present in most living organisms. Toxicity studies on SCLPs have generally indicated no mammalian toxicity. The PMRA, United States Environmental Protection Agency (USEPA) and European Union regulatory authorities have received no reports of adverse effects to human health from the use of SCLPs.

Hercon Disrupt Micro-Flake SBW Spruce Budworm Mating Disruptant is not formulated with any materials that are of toxicological concern nor are there any impurities that are of toxicological concern in the formulation.

Residues in Water and Food

Dietary risks from food and water are not of concern.

Since there are no uses of Hercon Disrupt Micro-Flake SBW Spruce Budworm Mating Disruptant on food or feed crops, the likelihood of residues contaminating food is negligible to non-existent.

Although the target application area of Hercon Disrupt Micro-Flake SBW Spruce Budworm Mating Disruptant is the upper canopy of forests and woodlots, it is reasonable to expect that small amounts of this product could be deposited on surface water. The risk from this contamination is not of concern because the amount of active ingredient entering the water system would be very small and it would quickly biodegrade to non-toxic compounds. Therefore, the possibility of contamination of potable water from residues or metabolites of this product is negligible to non-existent.

Occupational Risks From Handling Hercon Disrupt Micro-Flake SBW Spruce Budworm Mating Disruptant

Occupational risks are not of concern when Hercon Disrupt Micro-Flake SBW Spruce Budworm Mating Disruptant is used according to label directions, which include protective measures.

Pesticide applicators mixing or loading Hercon Disrupt Micro-Flake SBW Spruce Budworm Mating Disruptant may come in direct contact with the product when loading the aerial application equipment. Therefore, the label specifies anyone mixing, loading, cleaning or repairing equipment should wear a long-sleeved shirt, long pants, chemical-resistant gloves and goggles. Taking into consideration these label statements and the low toxicity of this product, the risks to applicators, mixers or loaders are not of concern. The pilot of the aircraft is not expected to have any exposure to the end-use product during application.

Bystander exposure is possible, however, the highest application rate is 50 g of active ingredient (1 kg of product) per hectare and the target application area is the upper canopy of forests and woodlots. Since the areas of application are not commonly frequented by people and the product is not expected to reach ground level in significant quantities, the probability of accidental exposure is low. Considering the low toxicity and the low probability of exposure, the health risks to bystanders from the labelled use of this product are negligible to non-existent.

The postapplication exposure risks to human health are negligible since the level of active ingredient is not expected to exceed ambient levels of pheromone that would be produced by populations of spruce budworm moths during an infestation. No incidents of adverse affects to human health have been reported from exposure to ambient levels of SCLPs.

Environmental Considerations

What Happens When Hercon Disrupt Micro-Flake SBW Spruce Budworm Mating Disruptant is Introduced Into the Environment?

Hercon Disrupt Micro-Flake SBW Spruce Budworm Mating Disruptant is released into the environment from fixed-wing aircraft equipped with specialized pods or helicopters with pods or buckets. The pheromone active ingredient is volatile and as it is released from the micro-flake carriers will dissipate rapidly into the environment. Formulants present in the micro-flake carrier, upon release, are expected to have minimal environmental impact under the proposed use pattern.

Hercon Disrupt Micro-Flake SBW Spruce Budworm Mating Disruptant is to be broadcast applied in forested areas, thus, aquatic organisms and wild birds could be exposed through deposit in aquatic systems or ingestion of the micro-flake. Deposit of Hercon Disrupt Micro-Flake SBW Spruce Budworm Mating Disruptant into aquatic systems is expected to be minimal, as a sticker agent is used to retain the micro-flake carriers in the plant canopy. A feeding study is being requested to further evaluate the risk to birds.

Value Considerations

What is the Value of Hercon Disrupt Micro-Flake SBW Spruce Budworm Mating Disruptant?

(E,Z)-11-tetradecenal, a pheromone from spruce budworm moths, can be used to disrupt adult spruce budworm moths from mating resulting in a decrease of fertile eggs being laid.

Numerous sources of (E,Z)-11-tetradecenal dispersed throughout a treatment area can interfere with the ability of male spruce budworm moths to locate female moths for mating. Female moths that remain unmated cannot produce and lay fertile eggs,

therefore, damage from the subsequent generation of budworms is reduced. (E,Z)-11-tetradecenal is not a conventional insecticide and therefore is not expected to have any direct adverse effects on non-target organisms, including beneficial parasites and predators.

There are other pest control products currently registered for control of the spruce budworm in forests but (E,Z)-11-tetradecenal is a new alternative with a completely different mode of action that targets a different stage of the pest life cycle. Therefore, the use of (E,Z)-11-tetradecenal would reduce the possibility of spruce budworm developing resistance to the currently registered products and provide an additional strategy for integrated pest management of spruce budworm.

A key aspect of the value of this product is that Hercon Disrupt Micro-Flake SBW Spruce Budworm Mating Disruptant may be applied by air, providing a viable alternative for use in forests, where ground-based application would be impractical.

Measures to Minimize Risk

Labels of registered pesticide products include specific instructions for use. Directions include risk-reduction measures to protect human and environmental health. These directions must be followed by law.

Environment

Label statements specifying risk reduction measures which include avoiding application to aquatic systems are required.

What Additional Scientific Information Is Being Requested?

Although the risks and value have been found acceptable when all risk-reduction measures are followed, the applicant must submit additional scientific information as a condition of registration. More details are presented in the Science Evaluation of ERC2007-07, or in the Section 12 Notice associated with the renewal of these conditional registrations. The applicant must submit the following information within the time frames indicated.

Chemistry

The methods of analysis of the active ingredient and its impurities must be refined using a technique for standardization/calibration. This requirement may be addressed with either an analytical-grade standard of the active ingredient which is characterized with its purity and subsequently used for quantitation of the technical or an internal standard technique must be developed to accomplish the same goal. Submission of this information to the PMRA must be made no later than December 1, 2011.

Environment

A laboratory feeding study is required to determine if birds will consume Hercon Disrupt Micro-Flake SBW Spruce Budworm Mating Disruptant when presented as food. Observations on the toxicity or other sublethal effects of the end-use product on the birds must also be reported. If the results indicate that Hercon Disrupt Micro-Flake SBW Spruce Budworm Mating Disruptant is consumed by the test birds, then a limited scale monitoring study conducted under conditions of operational use in a spruce budworm control program may be required. Submission of this information to the PMRA must be made no later than December 1, 2011.

In lieu of environmental fate data, a waiver request was submitted and reviewed by the PMRA. The actual study reports and papers published in scientific literature cited in this waiver are required. Submission of this information to the PMRA must be made no later than December 1, 2011.

Next Steps

Before making a final registration decision on the applications to renew the conditional registration for (E,Z)-11-tetradecenal, the PMRA will consider all comments received from the public in response to this consultation document. The PMRA will accept written comments on this proposal up to 45 days from the date of publication of this document. Please forward all comments to Publications (contact information on the cover page of this document). The PMRA will then publish a Registration Decision, which will include its decision, the reasons for it, a summary of comments received on the proposed final decision and the Agency's response to these comments.

Other Information

When the PMRA makes its registration decision, it will publish a Registration Decision on (E,Z)-11-tetradecenal (based on the Science Evaluation in ERC2007-07). In addition, the test data referenced in ERC2007-07 will be available for public inspection, upon application, in the PMRA's Reading Room (located in Ottawa).

List of Abbreviations

g	gram
kg	kilogram
PMRA	Pest Management Regulatory Agency pKa dissociation constant
SBW	spruce budworm
SCLP	straight chain lepidopteran pheromone
USEP	United States Environmental Protection Agency